REMARKS

Claims 1-10 are pending in the application. Claims 1-4 and 6 have been amended. Claims 9 and 10 have been added. The above amendments are supported by the disclosure at page 3, line 33 to page 4 line 12, page 5, lines 13-14, page 7, lines 26-31 and Examples of the present specification. Applicants submit that no new matter has been added by way of the above amendments.

Objection to the Specification

The specification has been amended herein to claim the benefit of the foreign priority document, PCT International Application No.PCT/JP2004/017328, as required by the Examiner. Accordingly, Applicants respectfully request withdrawal of the outstanding objection.

Rejection under 35 U.S.C. § 102

Claims 1-3 and 7-8 stand rejected under 35 U.S.C. § 102(b) as being anticipated by M. R. Johnson, U.S. Patent Application Publication 2003/0195160 (hereinafter "Johnson").

Claims 1-3 and 7-8 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,447,732 to Tanimoto et al. (hereinafter "Tanimoto").

Applicants respectfully traverse each of the above rejections.

The Advantages of the Present Invention

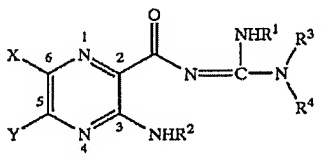
The present invention provides a sialogogue consisting of a polyglutamic acid having an average molecular weight of 10,000 to 5,000,000 or a salt thereof selected from sodium salt, potassium salt, magnesium salt, calcium salt, ammonium salt, ethanolamine salt, and basic amino acid salt, and a method of treating xerostomia, said method comprising:

administering the above polyglutamic acid as a sialogogue to a patient in need thereof.

The important feature of the present invention is to use a polyglutamic acid having an average molecular weight of 10,000 to 5,000,000 or a salt thereof selected from sodium salt, potassium salt, magnesium salt, calcium salt, ammonium salt, ethanolamine salt, and basic amino acid salt as a sialogogue. This is demonstrated in Examples of the present specification.

Discussion of Johnson

Johnson discloses a compound represented by formula (I),



(I)

and a method of treating dry mouth (xerostomia) comprising: administering an effective amount of compound represented by formula (I) to the mouth of the subject in need thereof. Johnson discloses that the compound represented by formula (I) can be formulated as a salt of organic acids, as follows.

> [0162] The compounds of formula (I) may be prepared and used as the free base. Alternatively, the compounds may be prepared and used as a pharmaceutically acceptable salt. Pharmaceutically acceptable salts are salts that retain or enhance the desired biological activity of the parent compound and do not impart undesired toxicological effects. Examples of such salts are (a) acid addition salts formed with inorganic acids, for example, hydrochloric acid, hydrobromic acid, sulfuric acid, phosphoric acid, nitric acid and the like; (b) salts formed with organic acids such as, for example, acetic acid, oxalic acid, tartaric acid, succinic acid, maleic acid, fumaric acid, gluconic acid, citric acid, malic acid, ascorbic acid, benzoic acid, tannic acid, palmitic acid, alginic acid, polyglutamic acid, naphthalenesulfonic acid, methanesulfonic acid, p-toluenesulfonic acid, naphthalenedisulfonic acid, polygalacturonic acid, malonic acid, sulfosalicylic acid, glycolic acid, 2-hydroxy-3-naphthoate, pamoate, salicylic acid, stearic acid, phthalic acid, mandelic acid, lactic acid and the like; and (c) salts formed from elemental anions for example, chlorine, bromine, and iodine.

Although Johnson discloses polyglutamic acid as one of the organic salts formed with organic acids, polyglutamic acid is merely exemplified as one of many organic salts formed with organic acids. Moreover, Johnson fails to disclose or teach the polyglutamic acid having an average molecular weight of 10,000 to 5,000,000 or a salt thereof selected from sodium salt, potassium salt, magnesium salt, calcium salt, ammonium salt, ethanolamine salt, and basic amino acid salt.

When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, *anticipation can only be found if the classes of substituents are sufficiently limited or well delineated*. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (Emphasis added). *See also In re Meyer,* 599 F.2d 1026, 202 USPQ 175 (CCPA 1979) (A

reference disclosing "alkaline chlorine or bromine solution" embraces a large number of species and cannot be said to anticipate claims to "alkali metal hypochlorite.").

Only if one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, can the compound be considered "anticipated." One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged." One may look to the preferred embodiments to determine which compounds can be anticipated. *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962) (Emphasis added).

In the present instance, Johnson does not sufficiently limit the disclosure of polyglutamic acid such that one of ordinary skill in the art could "*at once envisage*" the claimed polyglutamic acid having an average molecular weight of 10,000 to 5,000,000 or a salt thereof selected from sodium salt, potassium salt, magnesium salt, calcium salt, ammonium salt, ethanolamine salt, and basic amino acid salt. Moreover, Johnson does not teach or suggest the superior and unexpected sialogogue effect of the present invention. Accordingly, Johnson cannot properly anticipate the claimed invention. Applicants respectfully request reconsideration and withdrawal of the outstanding rejection.

Discussion of Tanimoto

Tanimoto discloses a mineral-enriched composition comprising 0.1 to 10 wt.%, based on the total weight of the composition, of poly-γ-glutamic acid degraded products of molecular

weight 1 x 10^4 to 3 x 10^5. However, Tanimoto fails to disclose a composition comprising a sialogogue consisting of a polyglutamic acid or the salt thereof of the present invention and an ingredient selected from saccharin sodium, xylitol, sorbit, erythritol, glucose, fructose, citric acid, and malic acid. Furthermore, Tanimoto fails to disclose or teach that the polyglutamic acid or a salt thereof promote salivary secretion and produce moisturizing effect.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Tanimoto does not sufficiently limit the disclosure of polyglutamic acid such that one of ordinary skill in the art could "*at once envisage*" the claimed polyglutamic acid having an average molecular weight of 10,000 to 5,000,000 or a salt thereof selected from sodium salt, potassium salt, magnesium salt, calcium salt, ammonium salt, ethanolamine salt, and basic amino acid salt. Moreover, Tanimoto does at all teach a composition comprising a sialogogue consisting of a polyglutamic acid or the salt thereof of the present invention and an ingredient selected from saccharin sodium, xylitol, sorbit, erythritol, glucose, fructose, citric acid, and malic acid. As such, Tanimoto does not teach "each and every element" of the claimed in order to properly anticipate the claimed invention. Applicants respectfully request reconsideration and withdrawal of the outstanding rejection.

Rejections under 35 U.S.C. §103(a)

Claims 4-6 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Johnson. Applicants respectfully traverse.

Johnson discloses that compound of formula (I) is effective for treating dry mouth. However, Johnson does not describe that the organic salts formed with polyglutamic acid is effective for treating dry mouth. Johnson does not disclose nor teach that the polyglutamic acid or the specific salt thereof per se promotes salivary secretion and produces moisturizing effect. From the disclosure of Johnson, it is not expected that polyglutamic acid *per se* has excellent sialogogue effect.

Examiners must consider comparative data in the specification which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness of the claims. *In re Margolis*, 785 F.2d 1029, 228 USPQ 940 (Fed. Cir. 1986). Evidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness. "Evidence that a compound is unexpectedly superior in one of a spectrum of common properties . . . can be enough to rebut a *prima facie* case of obviousness." *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987).

The Examples of the present invention demonstrate that the claimed invention unexpectedly possess superior sialogogue effect for treating dry mouth. See pages 9-11 of the

present specification. Thus, the examples sufficiently rebut the Examiner's allegation of obviousness. Reconsideration and withdrawal of the outstanding rejection is respectfully requested.

In view of the foregoing, Applicants believe the pending application is in condition for allowance. A Notice of Allowance is earnestly solicited.

Conclusion

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Monique T. Cole, Reg. No. 60,154 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: June 25, 2007

Respectfully submitted,

By _____
Gerald M. Murphy, Jr.
Registration No.: 28,977
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road
Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicant